

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. Claim Status and Amendments**

The Advisory Action dated July 29, 2009 indicates that the amendment dated July 14, 2009 will not be entered. The July 14<sup>th</sup> amendment shall remain unentered. Thus, claims 33-54 were pending in this application when last examined on the merits. In this amendment, claims 48-54 have been canceled, claims 36, 38, 39 and 43-46 have been amended, and new claims 55-57 have been added.

Support for the new and amended claims can be found in the specification and original claims as filed, for example, at page 12, lines 21-28, and page 5, lines 27-28. No new matter has been added. Upon entry of this amendment, claims 33-47 and 55-57 will be pending.

**II. Examiner Interview and Allowed/Allowable Claims**

Applicants gratefully acknowledge the courtesies extended by Examiner Chernyshev to Applicants' representative during the July 20, 2009 interview. The Interview Summary comments on the response filed July 14, 2009, and indicates that the proposed new claims (55-57) require new consideration

and examination, and that the remaining pending claims (33-47) can be allowed with additional minor amendments.

Currently amended claims 39, 44 and 46 specifically address the issues noted during the Examiner interview. In particular, currently amended claim 39 features an isolated host cell, and currently amended claims 44 and 46 correct antecedent basis for an isolated protein of SEQ ID NO: 2 or SEQ ID NO: 3.

Currently amended claims 36, 38, 39 and 43-46 also address the issues noted in the April 15, 2009, Office Action. Applicants gratefully acknowledge the indication in the Office Action, and in the Advisory Action, that claims 33-35 and 41-42 are allowed.

### **III. Claim Objections**

At page 2, item 4, the Office Action objects to claims 36-40 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully traverse the objection.

Amended claims 36 and 39 are independent claims that clearly define the intended subject matter. Dependent claims 37-38 further limit the subject matter of claim 36. Thus, Applicants request reconsideration and withdrawal of the objection.

At page 3, item 5, the Office Action objects to claims 44, 46 and 49 as not being in compliance with the requirements for Sequence Identifiers. Applicants respectfully traverse the objection.

Amended claims 44 and 46 address the Sequence Identifier issues pointed out in the Office Action, and claim 49 is canceled. Thus, Applicants request reconsideration and withdrawal of the objection.

**IV. Claim Rejections - 35 U.S.C. § 112, second paragraph**

At page 3, item 7, the Office Action rejects claims 43-47 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection.

The Office Action contends that claims 43 and 45 are vague and indefinite for the recitation of a "variant" of the paraoxonase protein. Although Applicants do not necessarily agree with this position, amended claims 43 and 45 no longer feature the "variant" paraoxonase limitation. Each of claims 43 and 45, and claims 44 and 46-47 dependent thereon, satisfies the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

In addition, Applicants note that the Advisory Action indicates that claims 44 and 46, as presented in the

July 14, 2009 amendment, are indefinite as lacking antecedent basis for limitations "SEQ ID NO: 2" or "SEQ ID NO: 3."

Currently amended claim 44 is directed to the pharmaceutical composition according to claim 43, wherein the isolated protein is an isolated protein of SEQ ID NO: 2 or SEQ ID NO: 3. Claim 43 further depends from claim 41, which further depends from claim 33. Claim 33 is directed to a protein of amino acid sequence SEQ ID NO: 1. SEQ ID NO: 1 includes alternatives for various amino acids (e.g., D or S at position 1, N or D at position 3, Q or E at position 11, etc.). SEQ ID NO: 2 and SEQ ID NO: 3 define these specific amino acids each is a subset of SEQ ID NO: 1. (See also, claim 34 which depends from claim 33).

Similarly, amended claim 46 is directed to the product of claim 45, wherein the isolated protein is an isolated protein of SEQ ID NO: 2 or SEQ ID NO: 3, which are subsets of SEQ ID NO: 1. Claim 45 further depends on claim 33, which features a protein of SEQ ID NO: 1.

**V. Claim Rejections - 35 U.S.C. § 112, first paragraph**

At page 4, item 11, the Office Action rejects claims 48-54 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

With respect to claim 48, the Office Action holds the position that the recitation of the use of monoclonal antibodies directed against "different epitopes of the isolated protein" renders the claim not enabled. The Office Action acknowledges that the instant protein of claim 33 is novel but the "different epitopes" are not shown to be unique. Thus, the Office Action concludes that the method of claim 48 would result in determination of concentration of any protein that shares the same six amino acid stretch of epitope common with the instant protein of SEQ ID NO: 1 and therefore is not enabled for a method of determining the concentration of the protein of claim 33.

The method claims 48-54 have been cancelled, and new method claims 55-57 have been added. Claim 55 is directed to a method for determining the concentration of the protein according to claim 33 utilizing electrophoresis, purification, quantification of protein activity, or immunoassay. The methods do not rely on the use of monoclonal antibodies directed against "different epitopes" of the protein. Utilizing the disclosure in the specification, including the cited references, and the knowledge and skills associated with one of ordinary skill in the art, one could practice any of the methods recited in claim 55 to determine the concentration of the protein of claim 33.

For at least these reasons, new claim 55, and new claims 56-57 dependent thereon, satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

**VI. Double Patenting Rejection**

At page 6, item 12, the Office Action states that if claims 43-44 are found allowable, then claims 45-47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicants respectfully disagree. The referenced claims are not duplicates.

Claims 43 is directed to a pharmaceutical composition in which the isolated protein is in combination with a paraoxonase protein comprising the amino acid sequence of SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6. Claim 45 is directed to a combination product comprising the isolated protein and at least one paraoxanase protein consisting of the amino acid sequence of SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6. Claim 43 and claim 45 recite at least one distinct critical limitation to distinguish the claimed products, therefore, double patenting does not apply.

**VII. Conclusion**

Having addressed all of the issues in the Office Action, the present application is in condition for allowance and notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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